**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**WASHINGTON, DC 20460**

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 22, 2011

**MEMORANDUM**

Subject: Efficacy Review for EPA Reg. No. 8383-3, Sporicidin Brand Disinfectant Solution; DP Barcode: 391132

From: Leah Harman
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7/26/11

To: Lance Wormell PM36
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Applicant: Contec, Inc.
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**Formulation from the Label:**

| Active Ingredient(s) | % by wt. |
|---|---|
| Phenol | 1.56% |
| Sodium Phenate | 0.06% |
| Other Ingredients | 98.38% |
| Total | 100.00% |

## I BACKGROUND

The product, Sporicidin Brand Disinfectant Solution (EPA Reg. No. 8383-3), is a registered disinfectant for use on hard, non-porous surfaces in household, commercial, institutional, and hospital or medical environments. The current submission was provided to address ATP failures in demonstrating effectiveness against *Staphylococcus aureus* (ATCC 6538). In the Agency's letter (dated September 30, 2010), the Agency proposed the following options (in brief):

1. You may remove the claim *Staphylococcus aureus* from your registration. Under this option, the product no longer qualifies for a label claim as a broad spectrum or a hospital disinfectant. All references to use of the product in healthcare settings must be removed from the label. The applicant must contact the Agency to discuss options for labeling of the product.

2. You may retest the product to retain the *Staphylococcus aureus* label claims. This testing must be conducted on three batches of product, one of which is at least 60 days old, with 60 carriers per batch, using the AOAC Use-Dilution Method under the same conditions as those on the primary label (presence of organic soil load.) If option number 2 is chosen, you must contact the Agency to arrange split sample testing of the batches that are being retested.

According to the registrant's letter (dated June 02, 2011), "Contec decided to proceed forward with option 2, where our company retested the product to retain the *Staphylococcus aureus* label claims." Efficacy testing was conducted by Mibrobac-Microbiotest, located at 105 Carpenter Drive, Sterling, VA 20164. The data package contained the referenced letter from the registrant and one efficacy study (MRID No. 485029-01).

## II USE DIRECTIONS

According to the label, the product is designed for disinfecting pre-cleaned, hard, non-porous surfaces in health/hospital treatment and patient rooms, operating rooms, schools, ambulances, hotels, restaurants, boats, planes, buses, and the home. It is recommended for medical and dental equipment, beds, surgical carts, counter tops, mannequins, telephones, keyboards, furniture, wheelchairs, walkers, sinks, floors, walls, light switches, linen hampers, shower stalls, toilet seats, trash containers and damp and musty areas, including animal areas. The product may be used on plastics, latex, vinyl, glass, treated wood, metal, glazed porcelain, glazed tile and paint. Directions on the label provide the following information regarding use of the product as a disinfectant: Pre-clean surface. Thoroughly wet pre-cleaned surface with product. Allow to remain wet for 10 minutes at room temperature. Use product on surfaces that cannot be immersed or soaked.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

<u>Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments</u>

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution

Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

## IV SYNOPSIS OF SUBMITTED EFFICACY STUDY

**MRID 485029-01, "AOAC Use Dilution Test" sponsored by Contec, Inc. and reported by Angela Hollingsworth of Microbiotest. Study Completion Date: May 27, 2011. Laboratory Project Identification Number: 757-102.**

Testing was initiated on May 15, 2011 against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 09411, 32801, and 30502 ≥60 days aged) of the ready-to-use product, Sporicidin Brand Disinfectant Solution, were tested using the AOAC Use Dilution Test (2009 18th ed., Protocol Identification Number CON.1.05.02.11; attached). For each lot, 60 stainless steel carriers were inoculated for 15 minutes and dried at 37±2°C for 20-40 minutes with a 48-54 hour old suspension of test organism cultured in Nutrient Broth. A contaminated carrier was added to each disinfectant 10 ml aliquot for a 10 minute contact time at 21°C. Carriers were then removed and transferred to recovery broth with neutralizers (Letheen Broth). All tubes were incubated at 37±2°C for 48±2 hours and the results recorded as visible growth or no visible growth. Controls included those for sterility, neutralizer effectiveness, carrier counts, viability, bacteriostasis, and confirmation of microorganisms.

## V RESULTS

| MRID Number | Organism | No. Exhibiting Growth/ Total No. Tested | | | Mean Carrier Count (CFU/ carrier) |
|---|---|---|---|---|---|
| | | Lot No. 09411 | Lot No. 32801 | Lot No. 30502 | |
| **10-Minute Exposure Time** | | | | | |
| 485029-01 | *Staphylococcus aureus* | 0/60 | 0/60 | 0/60 | $1.5 \times 10^6$ |

## VI CONCLUSIONS

The submitted efficacy data support the use of the product, Sporicidin Brand Disinfectant Solution, as a disinfectant with bactericidal activity against *Staphylococcus aureus* (ATCC 6538) on pre-cleaned, hard, non-porous surfaces for a 10-minute contact

time. Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots (at least one of which was ≥60 days old at the time of testing). The challenge microorganism was confirmed by colony morphology and Gram stain. Viability and neutralization confirmation testing showed positive growth of the microorganisms. Bacteriostasis streaks and sterility controls exhibited no growth. All of the controls met the criteria established for a valid test.

## VII RECOMMENDATIONS

1. The label claims that the product, Sporicidin Brand Disinfectant Solution, is an effective disinfectant against *Staphylococcus aureus* on pre-cleaned, hard, non-porous surfaces for a 10 minute contact time. This claim is acceptable as it is supported by the submitted data.

2. However, bactericidal claims on the label are made under the heading "Passes AOAC efficacy standards for disinfection in the presence of 5% organic soil." The current test conditions did not include 5% organic soil, therefore this broad claim on the label is unacceptable.